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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,549	03/29/2004	Samuel O. Sowemimo-Coker	HO-P02759US3	2250

37983 7590 10/11/2006

SMITH & NEPHEW, INC.
1450 E. BROOKS ROAD
MEMPHIS, TN 38116

EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/811,549	SOWEMIMO-COKER ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/30/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20, 102 are pending and are considered on the merits.

Information Disclosure Statement

The listing of the references on PTO 1449 is incomplete. A proper citation includes AUTHOR, TITLE, JOURNAL, VOLUME, NUMBER, INCLUSIVE PAGES, (month), YEAR. Citation CB is missing the first author and journal or conference information. Citations CC, CD are missing year of publication and type of publication (journal name, catalog name, internet address, etc.).

MPEP37 CFR 1.98(b) requires that each U.S. patent listed in an information disclosure statement be identified by patentee, patent number, and issue date. Each foreign patent or published foreign patent application must be identified by the country or patent office which issued the patent or published the application, an appropriate document number, and the publication date indicated on the patent or published application. Each publication must be identified by author (if any), title, relevant pages of the publication, date and place of publication. The date of publication supplied must include at least the month and year of publication, except that the year of publication (without the month) will be accepted if the applicant points out in the information disclosure statement that the year of publication is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the particular month of publication is not in issue. The place of publication refers to the name of the journal, magazine, or other publication in which the information being submitted was published.

Claim Rejections - 35 USC § 112

Claims 6-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 6-8 may all be interpreted to add a non-limited amount of a hypotonic solution to the whole blood or bone marrow aspirate. However, US 6,153,104 [A] teaches that the addition of water to leukocytes results in lysing the leukocytes (col. 2, l. 39). It is also well known, as a general principle, that addition of sufficient water or hypotonic solutions to cells, such as blood cells, in general, results in lysing of the cell because of the osmotic pressure differential.

Thus, it is not possible to collect a retentate comprising platelets, nucleated cells when the starting product, which is blood or bone marrow aspirate has water or a hypotonic solution added as required by claims 5-8, which addition can cause lysing of the cellular components of the starting material depending on the quantity added.

INDEFINITE

Claims 1-20, 102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 102, line 2, state that a physiological SOLUTION is provided. However, bone marrow aspirate or blood are not solutions. Please see the definition of the term solution, where it is a homogeneous mixture. Blood or bone aspirate contains cells which makes the composition not homogeneous. Therefore, by definition, they cannot be solutions.

Claim 19 has no antecedent basis for "the second product".

It is difficult to understand how a filter with a specific pore size of a leukoreduction filter can retain cells smaller than leukocytes which have a diameter of about 10 microns in a whole peripheral blood sample without agglomeration of the platelets or red cells. Platelets are significantly smaller than leucocytes, about 1.5microns. Usually, cells smaller than the pore size flow through a filter (permeate), while the larger cells are retained, unable to

pass through (retentate). Clarification of the **claimed** method would be appreciated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9-20 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by WO 02/089737 [BB].

The claims are directed to a method of concentrating cells not previously centrifuged comprising:
providing a physiological "solution",
subjecting the "solution" to filtration to form a retentate and a permeate "solution", whereby the retentate comprises platelets or nucleated cells or both and the permeate comprises red cells and plasma.

WO 02/089737 discloses a method comprising:
providing blood, aggregating the platelets,
filtering the blood to obtain platelets as a retentate and plasma, red cells, leukocytes as a permeate.

The platelet retentate may be used with a clinical carrier substrate and delivered via a patch, or a gel and can be combined with a hemostatic sealant (page 6). It may also be combined with bone fillers such as calcium phosphate (page 4, l. 2). Treatment with the compositions is also taught.

Claims 1-7, 102 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 6,544,751 [AF].

US 6,544,751 discloses in Example 4, providing whole blood, adding CPD solution to the blood, filtering whole blood through a leukoreducing filter, collecting filter retentate, which are the white cells.

Claims 1-4, 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Blazsek et al. [U].

Blazek et al. disclose collecting a bone marrow aspirate, filtering the bone marrow aspirate through 1000, 500, 200 micron filters, collecting filter retentate by washing with Dulbecco's PBS-5% calf serum with collagenase and heparin, centrifuged and the cell pellet collected (Materials and Methods). The cell pellet contains CD34+ cells, HPP-DFU cells and GM-CFU cells (abstract and discussion).

Claims 1-5, 20 and 102 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 01/72369 [N].

WO 01/72369 disclose a method comprising:
collecting bone marrow,
diluting bone marrow with an anticoagulant solution (p. 10, l. 10),
filtering the diluted bone marrow through a leukocyte depletion filter (page 16, l. 21), collecting the retentate (blood product) which has been trapped in the filter (page 21, l. 17). The processing forms a bone marrow product suitable for transplantation into a recipient or the composition is processed into one or more of its components (page 6, l. 18).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-20, 102 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/72369 [N] in combination with US 7,056,738 [B] and US 5,824,084 [AC] and US 2004/0071668 [C].

The claims are directed to a method of concentrating cells not previously centrifuged comprising:
providing a physiological "solution" (bone marrow aspirate),
subjecting the "solution" to filtration to form a retentate and a permeate "solution", whereby the retentate comprises platelets or nucleated cells or both and the permeate comprises red cells and plasma.

WO 01/72369 has been discussed above and generically teaches the use of filtration to obtain desired cell components from bone marrow.

US 2004/0071668 teach that bone marrow contains connective tissue progenitor cells (mesenchymal stem cells) which can be mixed with an implantable material such as hydroxyapatite to be placed in a bone defect.

US 5,824,084 teach that a grafting material comprising cells and substrate or scaffolding material should have an enriched population of connective tissue progenitor cells (abstract).

US 7,056,738 disclose that the diameter of mesenchymal stem cells is about 7-50 microns depending on type.

Therefore the use of the retentate of WO 01/72369 when using a filter designed to retain leucocytes to form a bone repair composition as described in US 2004/0071668 would have been obvious when taken with US 7,056,738 which teach the diameter of mesenchymal stem cells, which are also known as connective tissue progenitor cells, which would have reasonably been expected

to be retained by a filter which retains cells on the order of 10 microns (leukocyte diameter), while passing platelets (1.5 microns) and US 5,824,084 which teach the desirability of such a concentration of mesenchymal cells for such as use.

Further, with regard to the addition of a hypotonic solution to the bone marrow aspirate/blood, in the absence of evidence of criticality, one of ordinary skill in the art may add a solution of any tonicity desired. This is considered to be an element of experimental design.

One of ordinary skill in the art would have been motivated at the time of invention to practice this method in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

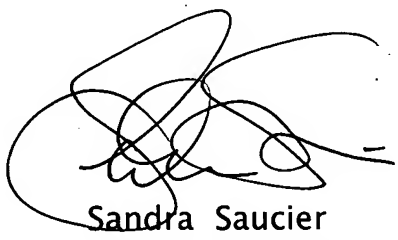
Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to the office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sandra Saucier
Primary Examiner
Art Unit 1651
September 21, 2006